K111417

JUL 15 2011

510(K) SUMMARY

11.1 SUBMITTER INFORMATION

A.	Company Name:	Access Scientific, Inc.
B.	Company Address:	12526 High Bluff Drive, Suite 360 San Diego, CA 92130
C.	Company Phone:	(858) 259-8333
D.	Company Facsimile:	(858) 259-5298
E.	Contact Person:	Albert Misajon Vice President, Regulatory Affairs and Quality Assurance amisajon@the-wand.com
F.	Date Summary Prepared:	July 1, 2011

11.2 Device Identification

A.	Device Trade Name:	the POWERWAND® Safety Introducer with an Extended Dwell Catheter
B.	Common Name:	Catheter Introducer Intravascular Catheter, Therapeutic, Short-term
C.	Classification Name(s):	Introducer, Catheter
D.	Classification Regulation(s):	21 CFR 870.1340 21 CFR 880.5200
E.	Device Class:	Class II
F.	Product Code:	DYB, FOZ
G.	Advisory Panel:	Cardiovascular

11.3 Identification of Predicate Device

The predicate device is the POWERWAND® Safety Introducer with an Extended Dwell Catheter that was cleared for commercial distribution under 510(k) K101422.

11.4 Device Description

The POWERWAND® Safety Introducer with an Extended Dwell Catheter is an all-in-one preassembled intravascular catheter introducer with intravascular catheter that consists of the following basic components: Introducer Needle, Nitinol Guidewire, Dilator and an Extended Dwell Catheter. It is intended to provide the clinician with a safe, simple and accelerated approach, using the Accelerated Seldinger Technique, to place the in-dwelling intravascular catheter through the skin into the circulatory system. The Extended Dwell Catheter allows for

withdrawal of blood and the administration of fluids, including power injection of contrast media. The device includes a Fast-flash™ feature that provides the clinician with feedback that the introducer needle is in the intraluminal position within the blood vessel. The device also incorporates a safety mechanism to guard against accidental needle stick.

11.5 INDICATIONS FOR USE

The POWERWAND® Safety Introducer with an Extended Dwell Catheter is used to gain access to the vascular system to sample blood and administer fluids intravenously. May be used for power injection of contrast media at a rate of 5cc/sec at up to 300 psi fluid pressure.

11.6 TECHNOLOGICAL CHARACTERISTICS

The proposed modified device has the same technological characteristics as the predicate device in terms of components, materials, chemical composition, and design. The changes to the device are in the mechanism of attaching/detaching the Needle Hub to/from the Dilator Hub. Performance testing has been conducted to confirm that the modified device satisfies performance requirements.

In addition to the changes identified above, the following changes have been implemented via letter-to-file since the clearance of the 510(k) for the predicate, the POWERWAND® Safety Introducer with an Extended Dwell Catheter.

1. Removed numbers from the Dilator Hub, Dilator Nut and Guidewire Cap.
2. The StatLock IV Ultra accessory has been removed from the POWERWAND.
3. The device labels were modified to assure the information is adequate to allow users to safely operate the device.
4. The DFU was revised to reflect the changes listed above, if they had an impact upon the text of the DFU.

11.7 SUMMARY OF TESTING

Design verification testing was conducted to demonstrate that the performance characteristics of the modified POWERWAND® Safety Introducer with and Extended Dwell Catheter are equivalent to the predicate device and satisfy the requirements of the product design specification for its intended use.

This testing included the following:

Special 510(k) Modification:

1. Needle Hub and Dilator Hub Attachment

Testing to qualify Special 510(k) modification

1. Needle Hub to Dilator Separation Force and Removal Force
2. Removal Testing

Letter-to-file Modifications:

There were no Letter-to-file Modifications (i.e. changes that have been implemented via letter-to-file since the clearance of the 510(k) for the predicate POWERWAND® Safety Introducer with an Extended Dwell Catheter) that required physical performance testing.

11.8 CONCLUSIONS DRAWN FROM STUDIES

The results of testing demonstrate that the modified POWERWAND® Safety Introducer with an Extended Dwell Catheter is substantially equivalent to the predicate device in design, function, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Access Scientific, Inc.
c/o Mr. Albert Misajon
Vice President, Regulatory Affairs and Quality Assurance
12526 High Bluff Drive, Suite 360
San Diego, CA 92130

JUL 15 2011

Re: K111417
Trade/Device Name: the POWERWAND® Safety Introducer with an Extended Dwell Catheter
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 1, 2011
Received: July 1, 2011

Dear Mr. Misajon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K111417

Device Name: **the POWERWAND® Safety Introducer with an Extended Dwell Catheter**

Indications for Use:

The POWERWAND® Safety Introducer with an Extended Dwell Catheter is used to gain access to the vascular system to sample blood and administer fluids intravenously. May be used for power injection of contrast media at a rate of 5cc/sec at up to 300 psi fluid pressure.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111417